SEP - 6 2001

Nicolet
BIOMEDICAL

K011823

Summary of Safety and Effectiveness

Company Name:	Nicolet Biomedical Incorporated 5225 Verona Road Madison, WI 53711
Contact: Phone: Fax:	Glen Hermanson, Manager of Standards and Compliance 608 441-2065 608 441-2007
Summary Date:	June 6, 2001
Trade Name:	BioRehab System
Common Name:	Biofeedback Device
Classification Name:	21 CFR 882.5050; Product Code: HCC

Predicate Device(s):

510(k) Number: K960508
Manufacture: The Prometheus Group
Trade Name: Pathway II Perineometer, MR Series of Amplifiers

510(k) Number: K935853 Product Code: HCC
Manufacture: UniTech Research Inc.
Trade Name: EMG Trainer

510(k) Number: K854277 Product Code: HCC
Manufacture: Therapeutic Alliance Inc.
Trade Name: NeuroEducator

1.0 Description of Device

The BioRehab System consists of an EMG amplifier, computer and software. Under the care and guidance of a physician or therapist, the BioRehab System supports relaxation and muscle reeducation by the application of electromyography (EMG) biofeedback. The BioRehab System supports patient game playing under EMG control. The patient consciously controls the EMG signal level from the therapist's selected muscle groups.

2.0 Intended Use

The BioRehab System is used for electromyography (EMG) biofeedback support of relaxation and muscle reeducation. The BioRehab System may be used by licensed medical practitioners to support their methods of muscle relaxation and reeducation/rehabilitation. The BioRehab System can be used in hospital, physician office, clinics, long-term patient care facilities, home and other therapy locations.

3.0 Technological

The BioRehab System applies EMG signal detection and amplification to support relaxation and muscle reeducation therapy. The significant components of the BioRehab System are a battery powered patient interface amplifier, computer and computer software. Commercially available surface EMG electrodes connect to the amplifier.

The EMG signal output of the BioRehab system is qualitative not quantitative. Under control of the therapist, an EMG signal threshold is set for the patient to support control of the computer cursor. The control of the computer cursor supports patient game playing on the computer.

4.0 Conclusions

The characteristics of the BioRehab System are substantially equivalent to the predicate devices. No new questions of safety or effectiveness are raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 6 2001

Nicolet Biomedical, Inc.
c/o Mr. Gary Syring
Quality & Regulatory Associates, LLC
800 Levanger Lane
Stoughton, Wisconsin 53589

Re: K011823
Trade/Device Name: BioRehab System
Regulation Number: 882.5050
Regulation Name: Biofeedback Device
Regulatory Class: II
Product Code: HCC
Dated: June 6, 2001
Received: June 11, 2001

Dear Mr. Syring:

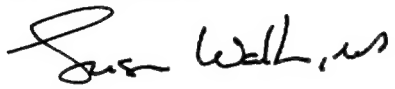
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
For Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K011823

Device Name: BioRehab System

Indications For Use:

The BioRehab System is used for electromyography (EMG) biofeedback support of relaxation and muscle reeducation. The BioRehab System may be used by licensed medical practitioners to support their methods of muscle relaxation and reeducation/rehabilitation. The BioRehab System can be used in hospital, physician office, clinics, long-term patient care facilities, home and other therapy locations.

(PLEASE: DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011823